Bair Paws® Model 850 Warming Unit **Operator's Manual**

Bair Paws®

Patient Adjustable Warming System

by Bair Hugger® Therapy

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Introduction to the Bair Paws® Patient Adjustable Warming System

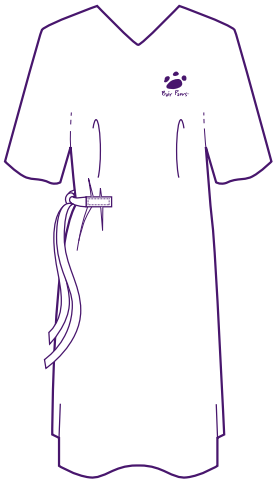
The Bair Paws patient adjustable warming system consists of the Model 850 forced-air warming unit and disposable warming gowns. The Bair Paws Model 850 and warming gown can provide comfort warming and prewarming to patients in preoperative settings. In postoperative settings the Model 850 can provide comfort warming.

This manual includes operating instructions and unit specifications for the Model 850 warming unit. Please refer to the Instructions for Use included with the Bair Paws warming gown for more information about the gown.

Bair Paws Model 850 Warming Unit

The Bair Paws Model 850 warming unit has the following key elements: a blower, a heating element, and a hand-held temperature controller. The warming unit delivers warmed air through a hose that is connected to a port in a Bair Paws gown. The patient can adjust the air temperature using the temperature controller.

Bair Paws Warming Gowns



The Bair Paws single-use warming gown has an integral, channeled insert that delivers warm air through small perforations to warm the patient. Air-channel inserts and hose ports enable comfort warming with a Bair Paws 800 series warming unit or clinical warming with a Bair Hugger® 500 or 700 series temperature management unit. The gown also has Velcro® fastener strips on each shoulder that provide easy access to the patient's arms and chest. The Bair Paws warming gowns are latex-free.

VELCRO is a registered trademark of Velcro Industries B.V.

Important Information about the Bair Paws Model 850 Warming Unit

Indications/Intended Use

The Model 850 warming unit is indicated for patient warming. This warming unit has been designed for use with the Bair Paws warming gowns in all preoperative and postoperative settings.

Contraindication

Do not apply heat to lower extremities during aortic cross-clamping. Do not apply heat to ischemic limbs. Thermal injury may result.

Warnings

- Do not warm patients with the warming unit's hose alone. Thermal injury may result. Always connect the hose to a Bair Paws warming gown before providing patient warming.
- Do not use a forced-air warming device over transdermal medications; increased drug delivery, patient death, or injury may occur.
- Use only Bair Paws warming gowns with the Model 850 warming unit. This warming unit has been designed to operate safely with Bair Paws warming gowns; use with other products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with products other than Bair Paws warming gowns.
- The Model 850 warming unit is not intended for use in the operating room.
- Do not allow the warming unit's hose to contact the patient's skin during patient warming. Thermal injury may result.
- Position the temperature controller cord and the hose away from the patient's neck or shoulders to avoid entanglement and/or injury.
- Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Precautions

- Do not initiate patient warming unless the Model 850 warming unit is safely placed on a hard surface or securely mounted. Otherwise, injury may result.
- The Model 850 warming unit meets the international electronic interference requirements of EN 60601-1-2 and EN 55011. However, if radio frequency interference with monitoring equipment occurs, connect the warming unit to a different power source.
- Monitor the patient's temperature and cutaneous response every 10-20 minutes or according to institutional protocol and monitor the patient's vital signs regularly.

Proper Use and Maintenance

Arizant Healthcare Inc. assumes no responsibility for the reliability, performance, or safety of the unit if:

- modifications or repairs are performed by unqualified personnel,
- the warming unit is used in a manner other than that described in the Operator's Manual, or
- the warming unit is installed in an environment that does not meet the appropriate electrical and grounding requirements.

Read Before Servicing Unit

All repair, calibration, and servicing of the Model 850 warming unit must be performed by qualified, medical equipment service technicians who are familiar with good practice for medical device repair. If the warming unit does not require the manufacturer's attention, Arizant Healthcare Inc. will ship replacement parts to your location. Perform all repairs and maintenance in accordance with the instructions provided with the replacement parts.

Preparing the Bair Paws Model 850 Warming Unit for Use

Before you begin using the warming unit, make sure that it is safely placed on a flat, hard surface such as a table, or securely mounted on a wall, IV pole, or bedrail.

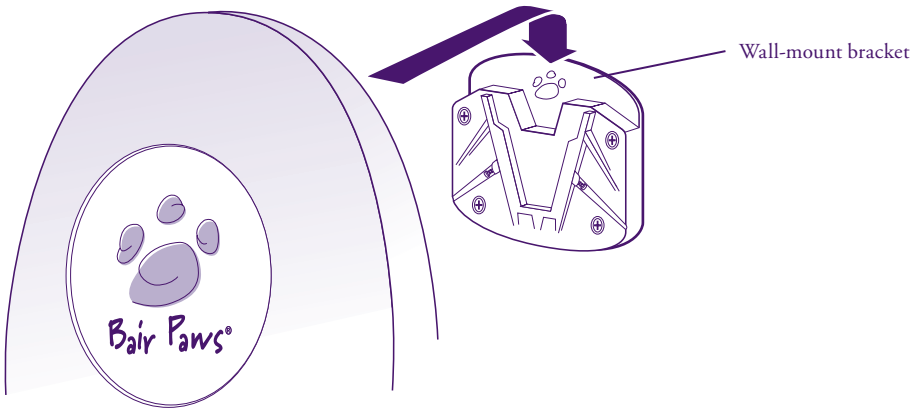
CAUTION: Do not place the warming unit on a soft or uneven surface, such as a bed, or the air intake may become blocked.

A wall-mount bracket is shipped with every warming unit; the brackets for mounting the warming unit to an IV pole or a bedrail are available separately. Please contact your local sales representative or call Arizant Healthcare® customer service at 1-800-733-7775 for more information about ordering mounting brackets.

The following instructions for mounting the warming unit assume that the brackets have already been attached to the wall or to the warming unit.

Placing the Warming Unit on the Wall-mount Bracket

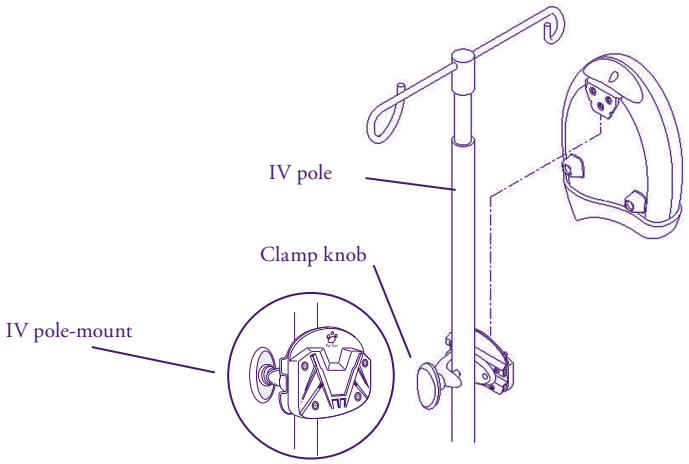
1. Slide the V-shaped bracket on the back of the warming unit into the groove of the wall-mount bracket.
2. Lift the warming unit straight up to remove it from the wall-mount bracket.



Mounting the Warming Unit on an IV Pole

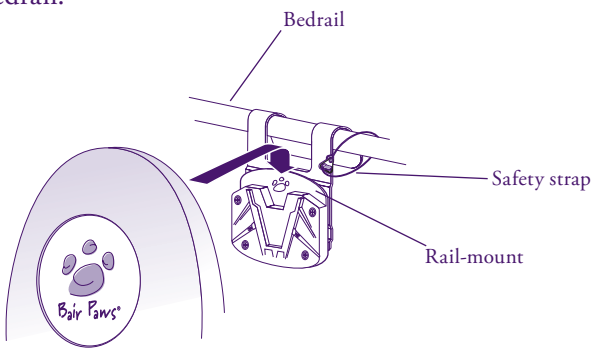
CAUTION: To prevent tipping, mount the Model 850 warming unit on an IV pole at a height that ensures stability. We recommend mounting the warming unit no higher than 44 in. (112 cm) from the floor on an IV pole with a minimum wheelbase radius of 14 in. (35.6 cm). Failure to do so may result in IV pole tipping, leading to potential catheter site trauma and other patient injuries.

1. Position the IV pole-mount at the desired height on the IV pole.
2. Turn the clamp knob on the IV pole-mount clockwise to tighten the clamp to the pole.
3. Slide the V-shaped bracket on the back of the warming unit into the groove of the IV pole-mount.



Mounting the Warming Unit on a Bedrail

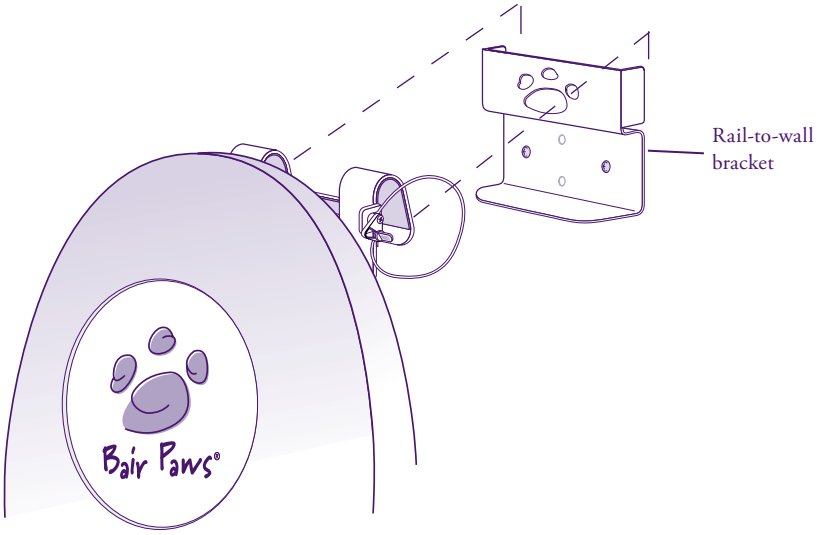
1. Hang the Model 850 warming unit on a bedrail by the hooks on the rail-mount that has been pre-attached by a biomedical technician to the back of the unit.
2. Wrap the safety strap around the bedrail and connect the end to the fastener on the strap. The safety strap will prevent the warming unit from falling if the rail-mount is inadvertently dislodged from the bedrail.



Mounting the Warming Unit with a Rail-mount to the Wall

Precaution: For use only with the Model 850 warming unit.

1. Hook the warming unit with the attached rail-mount to the rail-to-wall bracket.

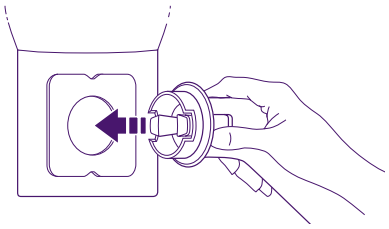


Operating Information

Instructions for Use

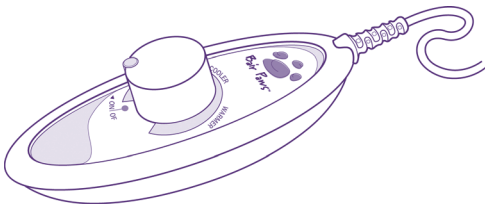
The instructions below describe how to use the Bair Paws Model 850 warming unit with a Bair Paws gown. For more information about the Bair Paws warming gowns, refer to the Instructions for Use that is shipped with the warming gowns.

1. Instruct your patient to put the warming gown on so the opening is in the back. The gown has ties on the side and back of the neck. The gown should be tied loosely to help warm air to circulate in the gown insert.
2. Connect the warming unit hose to the lower hose port on the warming gown by performing the following steps.
    a. Squeeze and hold the two buttons on the sides of the hose nozzle.
    b. Insert the nozzle into the open hose port in the warming gown.
    c. Release the buttons to lock the hose nozzle in place.



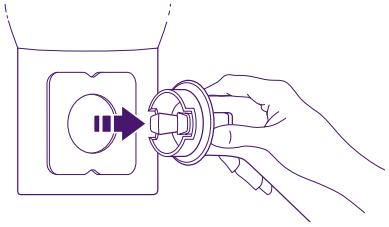
3. Connect the warming unit to a properly grounded power source.

4. Turn the knob on the temperature controller clockwise to turn the warming unit ON. When you turn the warming unit on, the heater and blower activate. Also, the “Power On” indicator light illuminates.



5. Allow the patient to adjust the temperature to a comfortable level. The temperature is adjusted by turning the knob on the temperature controller. The temperature adjustment varies from ambient to 40±3°C.

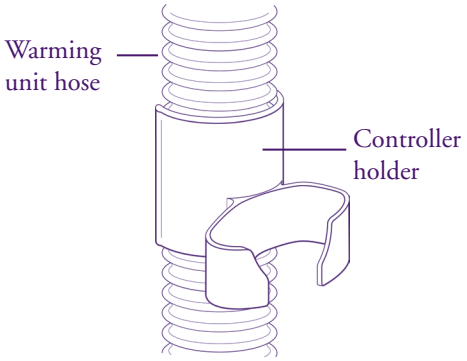
6. To disconnect the hose nozzle from the warming gown, press the two buttons on the sides of the nozzle and withdraw the nozzle from the hose port.

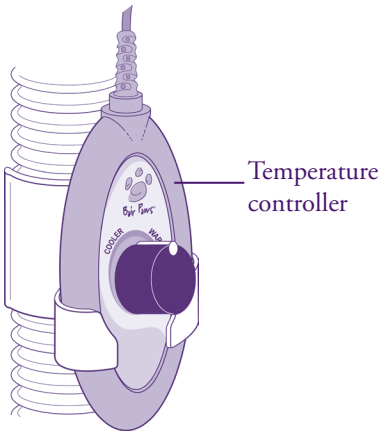


Using the Hand-held Temperature Controller Holder

The controller holder helps to prevent cord clutter around the patient and accidental damage to the controller.

1. Press the holder onto the warming unit hose so it is within the patient's reach.
2. Slide the temperature controller into the holder. It should fit securely with the dial facing the patient.





What to Do if the "Over-Temp" Indicator Light Illuminates

If the "Over-Temp" indicator light illuminates, the warming unit has detected warmer air than what would be expected under normal operation. This event may occur if airflow through the system becomes blocked or if the unit is improperly calibrated. When an over-temperature event occurs, the heater and blower automatically turn off to ensure safety. You should perform the following steps:

1. Discontinue patient warming.
   - Disconnect the warming unit hose from the Bair Paws warming gown.
   - Turn the warming unit OFF.
2. Unplug the warming unit from the power source and wait 5 minutes.
3. Reconnect the warming unit to the grounded power source.
4. Turn the warming unit ON and select the temperature setting.
5. Allow the warming unit to run for at least 5 minutes.
   - If the "Over-Temp" light illuminates again, return the warming unit to Arizant Healthcare for service.
   - Otherwise, reconnect the warming unit hose to the Bair Paws gown to resume patient warming.

General Maintenance

Calibrating the Operating Temperatures

Operating temperature calibration should be verified every 6 months and after performing service procedures. In addition, if the ambient temperature where the warming unit will be used is higher than 24°C (75°F), the unit should be recalibrated before it is placed in service. You will need a Bair Paws Model 90055 temperature test kit to perform the calibration. Calibration instructions are included with the test kit.

Replacing the Filter

Replace the filter every 6 months or sooner if necessary. To order a replacement filter, contact Arizant Healthcare customer service using either of the telephone numbers listed on page 11. Instructions for replacing the filter will be included with the replacement filter.

Cleaning the Warming Unit

Warning: Do not immerse any part of the warming unit while cleaning it. Moisture will damage the components, and thermal injury may result.

Precaution

- Do not use a dripping wet cloth to clean the warming unit. Moisture may seep into the electrical contacts and damage the components.
- Do not use harsh solvents to clean the warming unit.* Solvents may damage the labels and other plastic parts.

Method

1. Disconnect the warming unit from the power source before cleaning.
2. Wipe the cabinet, the temperature controller, and the outside of the hose with a damp, soft cloth and a mild cleaning solution or antimicrobial spray.
3. Dry with a separate soft cloth.

* WINDEX® multi-use liquid cleaner, ENVIROCIDE® disinfectant, and ALCONOX® industrial cleaner are three products that can be used to clean the equipment, as well as 3% household bleach, isopropanol, ethanol, ammonia or other phosphate-based glass cleaning solutions.

WINDEX is a registered trademark of S.C. Johnson & Son, Inc.
ENVIROCIDE is a registered trademark of Metrex Research Corporation.
ALCONOX is a registered trademark of Alconox, Inc.

Technical Support and Customer Service

U.S. Customer Service

TEL:
800-733-7775
952-947-1200

FAX:
800-775-0002
952-947-1400

When You Call for Technical Support

Please be ready to give the Technical Support Representative the serial number of your Bair Paws warming unit. The serial number is located on the back of the unit.

Repair and Exchange

Call Arizant Healthcare customer service if your Model 850 warming unit requires service. A customer service representative will give you a Return Authorization (RA) number. Please use this RA number on all correspondence concerning your warming unit. Your customer service representative will also send a shipping carton to you at no charge upon request.

Bair Paws Warming Unit Limited Warranty

Two-Year Limited Warranty[a] [c]

Arizant Healthcare Inc. ("Company") warrants to the original end-user ("User")[a] that each Bair Paws warming unit ("Unit")[b] will be free from defects in materials and workmanship under normal use and service for two years[c] from the date of shipment. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES APPLICABLE TO THE UNITS, SUCH AS WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY THE COMPANY. Some jurisdictions may not allow the disclaimer of implied warranties, so the above limitations may not apply to you.

Limitation of Remedies
If, during the limited warranty period, a Unit or part is found to be defective because of defects in materials and workmanship under normal use and service, it will be repaired or replaced without charge. Defective Units or parts must be returned to Arizant Healthcare Inc., 10393 West 70th Street, Eden Prairie, MN 55344. Repair or replacement of a Unit or part under the terms of this limited warranty in no way lengthens the limited warranty period.

User's exclusive remedy, IN LIEU OF ALL INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING FOR NEGLIGENCE, is limited to repair or replacement of a defective Unit or part under the terms and conditions of this limited warranty. Company will bear no other expenses. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so this limitation may not apply to you.

This limited warranty does not apply to certain of the parts listed below or to any Unit in which parts other than replacement parts made or approved by the Company have been used if such parts are the cause of failure. Company shall have no obligation under this limited warranty to make repairs or replacements necessitated in whole or in part by accidents, fault, or negligence of User.

PART	WARRANTY PERIOD (from the date of shipment to User)
Filters	N/A
Fuses	N/A
Hose	1 year
Cords	1 year
Labels	1 year
Temperature controller	1 year
Mounting brackets	1 year

This limited warranty applies only to User and is valid only for the use of Units with Bair Paws gowns. The use of any gowns or other products not manufactured or approved by Company for use with Units invalidates this limited warranty. Use of Units in a manner not specified in the instructions for use invalidates this limited warranty. This limited warranty is non-transferable.

This limited warranty gives you specific legal rights, and you may also have other rights which vary from jurisdiction to jurisdiction.

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a Distributors are not end-users unless they have purchased a unit for their sales representatives' use.

b This limited warranty is valid only for Bair Paws warming units. It does not apply to Bair Paws gowns or accessories or any other product.

c Refurbished Units have a one-year limited warranty from the date of shipment to User. As indicated below, this limited warranty does not apply to certain parts and other parts have a one-year limited warranty from the date of shipment to User.

Technical Specifications

Physical Characteristics

DIMENSIONS OF WARMING UNIT	11 in. high x 2.5 in. deep x 7.7 in. wide 27.9 cm high x 6.4 cm deep x 19.6 cm wide
DIMENSIONS OF TEMPERATURE CONTROLLER	2.5 in. wide x 5.8 in. long 6.4 cm wide x 14.7 cm long
WEIGHT OF WARMING UNIT	6.3 lb; 2.9 kg.
MOUNTING OPTIONS	Wall mount bracket, IV pole clamp, and rail-mount bracket with safety strap.
HOSE	Detachable, flexible, and washable. 78 in. long x 1.5 in. wide; 198 cm long x 3.8 cm wide
FILTRATION SYSTEM	Dust filter included.
RECOMMENDED FILTER CHANGE	Change at least every 6 mo.

Temperature Characteristics

TEMPERATURE CONTROL	Electronically controlled using integrated circuit sensor.
HEAT GENERATED	750 BTU/hr (average)
AVERAGE OPERATING TEMPERATURES AT THE END OF THE HOSE	Variable: ambient to 40° ± 3°C ambient to 104° ± 5.4°F

Safety System Characteristics

THERMOSTAT	Independent electronic and heater (electromechanical)
OVERCURRENT PROTECTION	Fused input line.
SAFETY FEATURE	Over-temperature: color indicator light illuminates, heater and blower shut down.
CERTIFICATIONS	IEC 60601-1: UL 60601-1; CAN/CSA-C22.2, No. 601.1; EN 60601-1-2; EN 55011; ASTM F2196-02
CLASSIFICATIONS	Classified under EN 60601-1 Guidelines (and other national versions of the Guidelines) as Class II, Type BF, Ordinary equipment, Continuous operation. Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, ASTM F2196-02, and Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.

Technical Specifications - Continued

Electrical Characteristics

BLOWER MOTOR	Airflow: 7-9 cfm
POWER CONSUMPTION	Peak: 290W Average: 150W
LEAKAGE CURRENT	Meets IEC 60601-1 and UL 60601-1 requirements
HEATING ELEMENT	285W Resistive
POWER CORD	15-foot, SJT, 3 cond., 10A
DEVICE RATINGS	110-120 VAC, 60 Hz, 3.0 A
FUSES	3.0 A
TEMPERATURE CONTROLLER CORD	32” from hose collar, 4 cond., Max. voltage: 5V

Definition of Symbols

The following symbols may appear on the product, on the exterior packaging, or in the product labeling.

ON/STANDBY

Temperature control

Equipotentiality plug (ground)

Fuse

Attention, consult accompanying documents

Nonexplosion proof

Dangerous voltage

Type BF equipment (patient applied)

Voltage, alternating current (AC)

Protective earth ground

Ground

Class II Equipment

No free hosing

Arizant Healthcare

bright ideas that work

Arizant Healthcare Inc.,
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Bair Hugger, Bair Paws, Arizant, Arizant Healthcare, bright ideas that work,and the Bair Paws and Arizant logos are trademarks of Arizant Healthcare Inc., registered or pending in the U.S. Patent & Trademark Office and in other countries.

U.S. Patent 6,876,884; D485,338.
Other patents pending.

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